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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,154	02/05/2001	Seo Hong Yoo	APAP31191-A 072852.0117	5489

7590 01/14/2004

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/778,154

Applicant(s)

YOO, SEO HONG

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-151 is/are pending in the application.
- 4a) Of the above claim(s) 1-137 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 138-151 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 14
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed July 03, 2003. Upon entering the amendment, the claims 138-147 are amended. New claims 148-151 are added.
2. The claims 138-151 are presented for the examination.

Claim Objections

3. Claim 139 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim 139 recites a paste to further limit the subject matter(i.e. solution) of previous claim 138. However, paste(semi-solid) is physically different from solution(liquid) and thus, the dependent claim 139 fails to further limit the subject matter of a previous claim where dependent claim should be narrower than the parent claim.

Claim Rejections - 35 USC § 112

New matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 138-147 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims now recite the phrase "free of alcohol". However, the specification as originally filed fails to provide written descriptive support for said phrase.

Additionally, the specification as originally filed indirectly teaches that the alcohol(i.e. methanol) is used to make UD te,e has did not specifically mention of alcohol, the specification as originally filed does not exclude alcohol from the instant invention.

Thus, the instant disclosure does not convey to one of ordinary skill in the art that the inventor had possession of the later claimed subject matter(i.e.free of alcohol), at the time the application was filed.

3. Claims 148-150 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are now reciting new limitations as following:

(a) the first material is less than about 30:1 in claim 148;

(b) the first material is more than 1.17%(W/W) in claim 149; and

(c) the second material is more than about 35%(W/W).

The specification as originally filed specifically provides a generic description which supports the content amount of first or second materials as shown below(from page 23, line 14 to page 24, line13):

In preferred embodiments of the inventionmaltodextrin required to prevent the precipitation of bile acids from is 5g for every 0.2g of ursodeoxycholic acid, 25g for every 1g of80g of pectin for every 500mg of ursodeoxycholic acid in 100mL water.

The specification also exemplifies several compositions comprising various ratios and content amount for each component thru out the specification(see examples at page 32, 37, and so on.

Although the specification as originally filed teaches these generic description of the percentages and ratios between first and second materials, the values are different in each example and there is no consistency on the values(i.e. amounts for each components and ratios between two components). For example, several examples include less than 35%(W/W), see example 1 at page 32. Also, the first material is not necessarily less than 30:1, for example, the preferred embodiment include 5g of maltodextrin:0.2g of ursodeoxycholic acid(25:1), see page 23, lines 15-16. The later claimed arbitrary range of "less than 30:1, more than 1.17%(W/W) or more than 35%(W/W) dos not have written descriptive support in the originally filed specification.

Thus, the limited generic disclosure and examples fail to convey to one of ordinary skill in the art that the inventor had possession of the later claimed subject matter, at the time the application was filed.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 151 is rejected under 35 U.S.C. 102(b) as being anticipated by Nakazawa et al(JP62153220-abstract only).

JP'220 teaches an oral aqueous clear solution comprising bile acids(e.g. ursodeoxycholic acid) and dextrans(e.g. amyloextrin, D-glucose, water, etc. It further teaches that the said bile acid composition can be formulated and satisfied as internal medication without pH adjustment, see entire abstract(English translated JP abstract and CAPLUS(database) version).

All the critical elements required by the instant claims are taught by the reference and the all the claimed subject matter is anticipated.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 138-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakazawa et al(JP62153220-abstract only).

As mentioned in 102 rejection, JP 220 teaches an clear aqueous oral solution comprising bile acids(e.g. ursodeoxycholic acid), dextrans (e.g. amyloextrin), D-

glucose, water and so on. All the critical elements are taught except the free of alcohol(considered to be new matter).

Even if the new matter rejection is not valid, the difference between the patented invention and instant claims is considered to be minor because the amount of alcohol content is very small which would not make the solution so different from the solution of the instant application. For instance, small amount of EtOH(ethanol) is used to dissolve ursodeoxycholic acid then adjusted to 100ml. Only 1 ml from the solution is used to make the final product. Thus, one of ordinary skill in the art would have not expected. "liquor solution or azeotropic mixture", especially any dramatic changes in outcome. Thus, the claimed subject matter is well within the scope of the patented invention and thus obvious, absent evidence to the contrary.

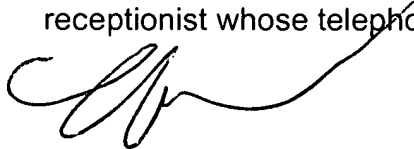
Conclusion

5. No claim is allowed.
6. Allowable subject matter is discussed during the telephonic conversation(1/2/04) and amendment to the claims to obviate the new matter rejection would put the claims 148-150 into the allowable condition.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Patent examiner
January 12, 2004
Art unit 1614